***Remarks***

Claims 1-20, 30 and 31 have been cancelled herein or previously without prejudice or disclaimer and claims 21 and 29 have been amended. Applicants reserve the right to file continuing applications directed to the canceled subject matter. Claims 21-29 and 32-36 are pending. No new matter has been added.

***Objection to the Abstract***

The Examiner has objected to the abstract of the disclosure because allegedly "it refers to speculative applications of the invention." *See,* Office Action, page 3.

Applicants respectfully disagree and submit that the content of the abstract as originally filed properly describes uses for a SCGF protein composition and is not speculative in nature. *See* M.P.E.P. § 608.01(b) at 600-75. Nonetheless, the abstract has been amended herein. Accordingly, Applicants respectfully submit that the objection of the abstract has been obviated and respectfully request that the objection be reconsidered and withdrawn.

***Objection to Claim 21***

The Examiner has objected to Claim 21 because "part (a) appears to be missing the word 'to' between the terms '-23' and '183'" and has required correction. *See,* Office Action, page 3. In response, Applicants have amended Claim 21(a) to state "amino acids -23 to 183 of SEQ ID NO:2." Accordingly, Applicants submit that the objection to claim 21 has been rendered moot.

***Rejection of claims 21-36 under 35 U.S.C. § 101***

The Examiner has rejected claims 21-36 under 35 U.S.C. 101 because allegedly "the claimed invention is not supported by a specific and substantial credible utility or a well-established utility." *See,* Office Action, page 4. Specifically, the Examiner alleges that the presently claimed antibodies lack utility because "the instant application does not disclose the biological role of this protein or its significance." *Id.*

As an initial matter, Applicants note that claims 30 and 31 have been canceled herein, without prejudice or disclaimer. Therefore, the rejection to these claims under 35 U.S.C. §101, first paragraph has been rendered moot.

With respect to the remaining rejected claims, Applicants respectfully disagree and traverse. Contrary to the Examiner's allegations, the specification does, in fact, disclose a

specific and substantial asserted utility for the human small CCN-like Growth Factor (SCGF) polypeptides. Initially, Applicants point out that the specification teaches that the SCGF polypeptides are "related to a family of growth regulators comprising *cef* 10/*cyr* 61, connective tissue growth factor (CTGF), and *nov*" and that the "mRNA corresponding to the polypeptide of this invention is highly expressed in the kidney, lung, heart and brain." *See* page 1, paragraph 0003. Further, the specification teaches that these growth regulators "are capable of rapidly inducing a complex set of genes" known as immediate early genes which encode "secreted, extracellular proteins which are needed for coordination of complex biological processes such as differentiation and proliferation, regeneration and wound healing." *See id.* at paragraph 0004 (citing Ryseck, R.P. *et al.*, *Cell Growth Differ.*, 2:235-233 (1991)). Finally, the specification also teaches that based in part on their similarity to members of the CCN growth factor family, and due to the nature of these proteins to induce differentiation and proliferation, SCGF polypeptides would be useful for "wound healing and associated therapies concerned with re-growth of tissue...for tissue remodeling such as restenosis...and may also be employed to stimulate angiogenesis. *Id.* at paragraphs 0068-0070. Therefore, the specification clearly and specifically asserts a specific biological role for the SCGF polypeptides and correlates this activity to specific deficiencies and/or conditions. As such, it logically follows that there is at least one patentable use for the polypeptides of the present invention.

The Examiner alleges that "[t]here is absolutely no evidence of record or any line of reasoning that would support a conclusion that a CCN-like growth factor of the instant application could be used in wound-healing and associated therapies, for tissue remodeling or for stimulating angiogenesis" and that "in the absence of a knowledge of the receptor to which CCN-like growth factor of SCGF binds, or the biological significance of this protein, there is no immediately obvious patentable use for it." *See* Office Action, page 5, last paragraph. In response, Applicants respectfully note that such a demonstration is not required to satisfy 35 U.S.C. § 101. Indeed, the Federal Circuit has stated with respect to the rejection of claims for lack of utility that:

> "It is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 U.S.P.Q.2D (BNA) 1340, 1345 (Fed. Cir. 1989); *see also Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570, 219 U.S.P.Q. (BNA) 1137, 1140 (Fed. Cir. 1983) ("It is axiomatic that an inventor need not comprehend the scientific

> principles on which the practical effectiveness of his invention rests."). Furthermore, statements that a physiological phenomenon was observed are not inherently suspect simply because the underlying basis for the observation cannot be predicted or explained.

*In re Cortright*, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999). Thus, there is no requirement that Applicants describe the precise biological mechanism of action for the claimed invention or demonstrate how it is involved in a particular disorder. *See* M.P.E.P. § 2107.02 (I) at 2100-33 to 2100-34. Likewise, there is no requirement that Applicants identify a particular receptor for the SCGF polypeptides to satisfy the utility requirement. Rather, the issue is whether an asserted utility is more likely than not true to one of ordinary skill in the art; a *reasonable correlation* between the disclosed biological activity and the asserted utility is sufficient. *See Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980) (emphasis added).

As discussed in detail above, the encoded polypeptides of the instant invention are members of the CCN growth factor family which induce cell differentiation, proliferation and regeneration, and therefore one of skill in the art would reasonably believe that the polypeptides would be useful, for example, in wound healing and associated therapies concerned with re-growth of tissue. Accordingly, where the specification discloses a biological activity (*e.g.*, cell regeneration), and reasonably correlates that activity to a particular use (*e.g.*, wound healing), the specification has sufficiently identified a specific utility for the invention. M.P.E.P. § 2107.01 at 2100-32 (emphasis added). In other words, so long as the correlation between the biological activity and the asserted use in a particular condition is sufficient to convince one of skill in the art, then the specificity requirement of 35 U.S.C § 101 is satisfied. *See also*, *Fujikawa v. Wattanasin*, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

In view of the above evidence and explanations, Applicants submit that the presently claimed invention has at least one or more patentable utilities. Therefore, Applicants respectfully submit that the rejection of claims 21-29 and 32-36 under 35 U.S.C. §101 has been obviated and respectfully request that the rejection of the claims be reconsidered and withdrawn.

***Rejection of claims 21-36 under 35 U.S.C. § 112, first paragraph***

Claims 21-36 are rejected under 35 U.S.C. § 112, first paragraph, based upon a premise that "since the claimed invention is not supported by either a specific, substantial

and credible asserted utility or a well established utility for the reasons set forth" in the rejection under 35 USC § 101, one skilled in the art clearly would not know how to use the claimed invention. *See*, Office Action, page 7.

Preliminarily, Applicants note that claims 30 and 31 have been canceled herein, without prejudice or disclaimer. Therefore, the rejection to these claims under 35 U.S.C. § 112, first paragraph has been rendered moot.

With respect to the remaining rejected claims, Applicants respectfully submit that, as explained above, claims 21-29 and 32-36 are supported by specific, substantial, credible and/or well-established utilities. Hence, in view of the present application's disclosure and the state of the art as of its earliest filing date, Applicants submit that a person having ordinary skill in the art would certainly know how to use the claimed invention. Accordingly, Applicants respectfully request the rejection of claims 21-29 and 32-36 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

***Rejections of claims 29 and 31-36 under 35 U.S.C. § 112, first paragraph***

The Examiner has rejected claims 29 and 31-36 under 35 U.S.C. §112, first paragraph for allegedly lacking written description because "[t]he claims are directed to a species of protein, the structure of which cannot be determined or predicted from the full-length amino acid sequence and the specification does not evidence isolation or conception of the structure of 'the mature polypeptide.'" *See*, Office Action, pages 7-8.

Applicants respectfully disagree and assert that one of ordinary skill in the art could readily determine that Applicants had possession of a mature polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97173. Nonetheless, claim 29 has been amended and claims 30 and 31 have been cancelled. Specifically, claim 29 has been amended to cancel claim element (b) which was directed to "the amino acid sequence of the mature polypeptide encoded by the human cDNA contained in ATCC Deposit No. 97173." Consequently, dependent claims 30 and 31, which were directed to elements (a) and (b) of claim 29, respectively, have been cancelled. Accordingly, Applicants submit that the rejection of claims 29 and 31-36 under 35 U.S.C. §112, first paragraph has been obviated. Therefore, Applicants respectfully request the rejection of claims 29 and 31-36 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

***Rejections of claims 29 and 31-36 under 35 U.S.C. § 112, second paragraph***

The Examiner has rejected claims 29 and 31-36 under 35 U.S.C. §112, second paragraph as allegedly indefinite because the metes and bounds of the recitation of "mature" in claim 29(b) cannot be determined. *See*, Office Action, page 9.

In response, Applicants point out that element (b) of claim 29 which contained the allegedly indefinite language has been deleted and claims 30 and 31 have been cancelled herein without prejudice or disclaimer. Accordingly, Applicants submit that the rejection of claims 29 and 31-36 has been rendered moot.

***Conclusion***

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the prosecution of this application.

If there are any additional fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: June 15, 2006

Respectfully submitted,

By _____

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